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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
07/827,906	01/30/1992	KENNETH A. BARTON	28079/41333	3375
74002	7590	06/18/2008		
Marshall, Gerstein & Borun LLP (Monsanto)			EXAMINER	
6300 Sears Tower			KUBELIK, ANNE R	
233 South Wacker Drive				
Chicago, IL 60606			ART UNIT	PAPER NUMBER
			1638	
			MAIL DATE	DELIVERY MODE
			06/18/2008 PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

07/827,906

Applicant(s)

BARTON ET AL.

Examiner

Anne R. Kubelik

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 23-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

1. Claims 23-32 are pending.

Claim Objections

2. Claims 23-27 are objected to because of the following informalities:

In claims 24 and 26, line 2, a comm. A should be inserted before “wherein”.

In claims 23 and 25, line 2, --, said method-- should be inserted before “comprising”.

In claim 27, line 1, --, said method-- should be inserted before “comprising”.

3. Claims 24 and 26 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As all the codons are changed to those of highest frequency in claims 23 and 25, the recitation in claims 24 and 26 that the codons have C or G in the third position fails to further limit the parent claims.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 23-32 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention, methods comprising modifying a coding sequence, does not require any physical transformation of matter and is essentially directed to a

thought process about information. It does not, for example, involve making a nucleic acid whose coding sequence is the modified coding sequence.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 23-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for a method of modifying the native coding sequence of any Bt insecticidal protein as in claims 23, 25 and 31. The specification only provides support for modifying the native sequence coding for a Bt delta-endotoxin (see, for example, pg 2, lines 19-23).

Neither the instant specification nor the originally filed claims appear to provide support for modifying the codons for at least the first 25 amino acids in any coding sequence as in claim 28. The specification only provides support for modifying “about 25 codons” at the N’ terminal end of the Bt sequence used in the Examples (pg 13, lines 15-22).

Neither the instant specification nor the originally filed claims appear to provide support for substituting at least 59 amino acids in any coding sequence as in claim 29. The specification

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only provides support for modifying 59-138 codons of the Bt sequence used in the Examples (pg 13, line 9).

Neither the instant specification nor the originally filed claims appear to provide support for attaching a single regulatory sequence to the modified sequence, as in claim 30. The specification only provides support for attaching flanking regulatory sequences (see pg 11, lines 17-21).

Thus, such claims constitute NEW MATTER. In response to this rejection, Applicant is required to point to support for the claims or to cancel the new matter.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 23 lacks antecedent basis for the limitation “the native coding sequence” in line 2.

Claims 23 and 25 are indefinite in their recitation of “Bt”. Is this *Bacillus thuringiensis*?

Claim 25 is indefinite in its recitation of “substituting, for each codon ...” In what is one substituting?

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

11. Claims 27 and 30-32 are rejected under 35 U.S.C. 102(g) as being anticipated by Fischhoff et al (2003/0192078, which is a division of application 08/434,105).

On 12 December 1986 (see interference decision in the instant case mailed 29 January 2004), Fischhoff et al reduced to practice a method of designing a synthetic *Bacillus thuringiensis* gene, said method comprising modifying the native sequence by substituting at least some of the codons in the native coding sequence with codons for the same amino acids but that have the highest frequency in the instant Table 1. As the instant Fig 1 and Table 1 in Fischhoff et al share codons that are the highest frequency in plants (see for example, Thr ACC, Pro CCA, Ile AUC, Lys AAG, Asn AAC and His CAC), Fischhoff method anticipates the instantly claimed method. Fischhoff et al also disclose attaching a promoter to the modified sequence (§57-63).

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 23-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,833,449. Although the conflicting claims are not identical, they are not patentably distinct from each other. A synthetic nucleic acid encoding a particular Cry endotoxin, wherein at least a portion of the coding sequence for the endotoxin exclusively uses the codons in the instant Fig 1 used at the highest frequency, as claimed in the issued patent, makes obvious a method of making a coding sequence for a Bt endotoxin using the codons in the instant Fig 1 used at the highest frequency, as claimed in the instant application. As the method steps are the same, methods of increasing the level of efficiency in expression of a Bt insecticidal protein are also made obvious.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the

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USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D.

June 18, 2008

/Anne R. Kubelik/

Primary Examiner, Art Unit 1638